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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/952,741	11/25/97	HATADA Y	2173-106P

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HM22/1204

EXAMINER	
SLOBODYANSKY,E	
ART UNIT	**PAPER NUMBER**
1652	20

DATE MAILED: 12/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/952,741	Applicant(s) Hatada et al.
	Examiner Elizabeth Slobodyansky	Group Art Unit 1652

☒ Responsive to communication(s) filed on *Sep 25, 2000*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *2-7, 9, and 11-24* is/are pending in the application.

Of the above, claim(s) *9, 11, and 17-19* is/are withdrawn from consideration.

☒ Claim(s) *12 and 13* is/are allowed.

☒ Claim(s) *2-7, 14-16, and 20-24* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The amendment filed September 25, 2000 amending claims 2 and 3 and adding claims 22-24 has been entered.

Claims 2-7, 9 and 11-24 are pending.

Claims 2-7, 12-16 and 20-24 are under consideration, claims 9, 11 and 17-19 are withdrawn.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claim 20 is objected to because "of" is typed instead of "higher than" after "an isoelectric point". Appropriate correction is required.

This objection is reiterated from the Office action mailed May 24, 2000.

Claim Rejections - 35 USC § 112

Claim 3, with dependent claims 4, 15, 16 and 20-24, is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art

that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is reiterated from the Office action mailed May 24, 2000.

Claim 3 is drawn to a DNA encoding an α–amylase having an amino acid sequence of SEQ ID NO:2 with one or more amino acids substituted, deleted or inserted and having a pH optimum of 8-9 and the specific substrate specificity.

The only α–amylase with the requisite properties that has been disclosed in '881 or instant application has the amino acid sequence of SEQ ID NO:2. However, claim 3 encompasses a great number of α–amylases having unknown structures and possessing the requisite properties. The Examiner is unable to locate adequate support in the specification for such α–amylases . Thus there is no indication that α–amylases having amino acid sequences other than SEQ ID NO:2 and having the requisite properties were within the scope of the invention as conceived by Applicants at the time the application was filed.

Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

The following rejection is the written description rejection.

Claim 3 is drawn to a DNA encoding an α–amylase having an amino acid sequence of SEQ ID NO:2 with one or more amino acids substituted, added, deleted or inserted and having the specific substrate specificity. There is no limitation on the structural homology. Therefore, claim 3 is equivalent to a claim wherein no amino acid sequence is recited. Such mutant and a DNA encoding thereof encompass a great number of molecules, both naturally occurring and synthetic, encoding amino acid sequences some of which may not have any structural homology with SEQ ID NO: 2. Claims 20 and 21 recite a nucleic acid sequence encoding an amylase having the requisite substrate specificity and some specific physicochemical properties from any biological source.

Newly added claims 22-24 are drawn to a DNA encoding α–amylase with pH optimum at pH 8-9 from any sources comprising a DNA of 20-26 bp not all of which are defined. There is no recitation of any other properties of an enzyme. Claims 22-24 do not correct the deficiencies of claim 3 because of the following. The DNA of the instant invention is 1776 bp long. Therefore, at most claims 22-24 recite 1.0-1.5% homology with SEQ ID NO:1. That is not sufficient to limit a DNA to any structure. Further, as discussed in the previous Office action, there are α–amylases with properties different from the α–amylase of the instant invention and having the amino acid sequences that are 87% and 69% identical to SEQ ID NO:2.

Applicants disclose one DNA molecule, the DNA encoding alkaline liquefying α-amylase from *Bacillus* sp. KSM-AP1378 having SEQ ID NO:1 and encoding the amino acid sequence of SEQ ID NO:2. Several bacterial α-amylases are known in the art. Claim 3 encompasses DNAs encoding said enzyme from all possible sources which would include fungi, plants, animals, etc. The specification does not disclose identifying characteristics which would allow to recognize a DNA encoding alkaline liquefying an α-amylase of all origins nor they are known in the art. Therefore, based on the instant disclosure, it is unpredictable which DNA will encode an alkaline liquefying α-amylase with the desired properties. Thus, a DNA encoding alkaline liquefying α-amylase with the requisite properties lacks sufficient written description.

In their Remarks filed September 25, 2000, Applicants argue that "on page 1, lines 21-22 it is shown that different sources for α–amylase were contemplated" (page 4, last paragraph). This is not persuasive because Applicants indicate the sources of α–amylase in general and not the sources of the specific α–amylase of the instant invention. Applicants further argue that "on page 2, lines 10-22, other alkaline α–amylases that show maximal activity in the alkaline pH range are disclosed" (paragraph bridging pages 4 and 5). These arguments are not persuasive because said other alkaline α–amylases have different properties including different alkaline pH optimum. If said other alkaline α–amylases would have the same properties as recited in claim 3,

the α–amylase of the instant application would not be patentable. Applicants argue that claims 22-24 "disclose a limitation on structural homology" (page 5, 2nd paragraph). This is not persuasive for the reasons discussed above.

Claims 3, 4, 15, 16 and 20-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA encoding an α–amylase having an amino acid sequence of SEQ ID NO:2 that has a pH-optimum at pH 8-9 and the specific substrate specificity, does not reasonably provide enablement for a DNA encoding an α–amylase having an amino acid sequence of SEQ ID NO:2 with one or more amino acids substituted, added, deleted or inserted and having the requisite properties or for a DNA comprising a fragment of about 20 bp. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

This rejection is reiterated from the Office action mailed May 24, 2000.

In their Remarks filed September 25, 2000, Applicants argue that "predictability [of changes in the amino acid structure] is not necessary , as the standard approach is to make a library of changes and screen them for activity" (sentence bridging pages 5 and 6). And further, "activity assay is recited which could be used" (page 6, 1st

paragraph). This is not persuasive because the recited activity assay is a general method for α–amylase activity that is not discriminating between α–amylase with different properties. Applicants do not teach any specific source of the α–amylase of the instant invention, if it exists, other than *Bacillus* sp. KSM-AP1378. Therefore, there is no teachings of the natural source of the enzyme and no teachings on the essential structural elements imparting the requisite properties.

Claims 2, with dependent claims 4-7, 14 and 16, and claims 23 and 24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2, as amended, recites "A DNA molecule, have α–amylase activity which encodes the amino acid sequence..." (emphasis added). A DNA does not have α–amylase activity.

Claim 23 recites a DNA molecule comprising the reverse complement of a DNA sequence. A complement does not itself code for the protein in question and its expression would never result in a protein with the α–amylase activity recited by the claim.

Claim 24 recites both a coding strand and a complement. It is confusing for the reasons discussed with regard to claim 23. Further, claim 24 is confusing because it is

unclear either a complement of a corresponding coding strand or a complement of any coding strand is intended.

Claim Rejections - 35 USC § 103

Claims 3, 4, 15, 16 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ara et al. in view of Tsukamoto et al. or Yuuki et al.

This rejection is reiterated from the Office action mailed May 24, 2000.

As explained above, claims 3, 4, 15, 16 and 20-24 read on a DNA encoding an amylase with the specific properties.

Ara et al. (EP 0670 367 A1, form PTO-1449) teach the enzyme of the instant invention.

Tsukamoto et al. and Yuuki et al. (form PTO-1449) teach a DNA encoding an alkaline liquefying α-amylase from *Bacillus* sp. #707 and *Bacillus licheniformis*, respectively. They disclose vectors containing said DNAs and cells transformed with the same.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to isolate a DNA encoding an alkaline liquefying α-amylase from *Bacillus* sp. KSM-AP1378 following the procedures taught by Tsukamoto et al. and Yuuki et al. The motivation is provided by Ara et al. who taught the amylase of *Bacillus*

sp. KSM-AP1378. One skilled in the art would have a reasonable expectation of success because the amylases of Tsukamoto et al. and Yuuki et al and DNAs encoding thereof have been isolated from *Bacillus* species.

In their Remarks filed September 25, 2000, Applicants argue that "[i]t would be unpredictable by one skilled in the art, upon reading the references cited by the Examiner, how to obtain an enzyme that would have a pH optimum activity in the range of pH 8-9" (page , last paragraph). This is not persuasive because the enzyme has been obtained by Ara et al. prior to the instant invention. A DNA encoding a known enzyme is obvious over the enzyme. The specific DNA sequence, i.e., the specific string of nucleotides, is unpredictable. However, the claims are not drawn to the specific DNA sequence but to a DNA sequence.

Allowable Subject Matter

Claims 12 and 13 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner

December 1, 2000